

Remarks

Prior to entry of this amendment, claims 1-9, 11-21, and 23-25 are pending in the application; of these, claims 12-14 have been withdrawn from consideration as drawn to non-elected species. Claims 1-9, 11, 15-21, and 23-25, as they read on the species of altered resistance to an herbicide, have been examined.

Claims 1, 2, 20, 23 and 24 have been amended to remove the word “recessive” with regard to the “mutagen.” Support for this amendment can be found throughout the specification and in the original claims. Claim 24 has also been amended to correct an obvious clerical error.

Applicants expressly reserve the right to pursue protection of any or all subject matter removed from the pending claims in one or more continuing applications. No new matter is introduced by the foregoing amendments. After entry of this amendment, claims **1-9, 11, 15-21, and 23-25 are pending in this application**. Consideration and allowance of the pending claims is requested.

Examiner Interview

Applicants thank Examiner Moran for taking the time to interview this case with their undersigned representative, by telephone, on May 31, 2006, and particularly for being flexible as to the time for that interview. During the interview, the pending New Matter rejections under §112 were discussed, as were prior art-based rejections that had been pending when the Request for Continued Examination (RCE) was filed. Applicants’ representative particularly thanks Examiner Moran for the detailed discussion regarding appropriate terminology related to types of mutation and resultant loss- and gain-of-function phenotypes. Additional detail with regard to the interview is included in context below.

Though complete agreement was not reached during the interview, the Examiner’s suggestions have been taken to heart and are incorporated herein. If any concerns remain regarding specific language choices in the claims, or support for claim language, the Examiner is invited to telephone the undersigned so that alternatives can be discussed.

Rejection(s) under 35 U.S.C. §112, first paragraph

Each of the examined claims (1-9, 11, 15-21, and 23-25) stands rejected under §112, 1st paragraph, on the ground that there is insufficient written description in the specification to support the claim. This is couched as a New Matter rejection. In particular, it is alleged that the following constitute new matter:

term/phrase/step	claim(s)
insertional recessive mutagen	1, 2, 20, 23, and 24
insertional recessive mutagen which is capable of gain of function	1
rescuing DNA flanking an insertional recessive mutagen from a T1 generation plant	23
insertional recessive mutagen which results in a dominant mutation	24

“insertional recessive mutagen”

The Office action states that the phrase “insertional recessive mutagen, as recited in claims 1, 2, 20, and 23-24, is new matter.” While Applicants do not necessarily concede that this is true, claims 1, 2, 20, 23 and 24 have been amended to remove the word “recessive” with regard to the type of mutagen. Thus, the claims are now directed to methods that employ “random insertion of an insertional mutagen” as in the original claims. These amendments obviate this rejection, and Applicants request that it be withdrawn.

“insertional recessive mutagen which is capable of gain of function”

The Office action also states that “[a]n insertional recessive mutagen which is capable of gain of function,” as recited in claim 1, is new matter. Applicants believe this rejection is moot, in light of the amendment to change “insertional recessive mutagen” to “insertional mutagen”. However, to the extent that the rejection would be maintained even in light of this amendment, Applicants traverse below.

“rescuing DNA flanking an insertional recessive mutagen from a T1 generation plant”

The step of rescuing DNA flanking an insertional recessive mutagen from a T1 generation plant, as recited in claim 23, has been alleged to be new matter. Applicants believe this rejection is moot, in light of the amendment to change “insertional recessive mutagen” to

“insertional mutagen”. However, to the extent that the rejection would be maintained even in light of this amendment, Applicants traverse below.

“insertional recessive mutagen which results in a dominant mutation”

The Office action further states that “[a]n insertional recessive mutagen which results in a dominant mutation, as recited in claim 24, is new matter.” Applicants believe this rejection is moot, in light of the amendment to change “insertional recessive mutagen” to “insertional mutagen”. However, to the extent that the rejection would be maintained even in light of this amendment, Applicants traverse below.

Discussion of Support

Applicants thank the Examiner for discussing claim scope and support during the telephone interview. As discussed, Applicants believe the application as originally filed, considered in its totality and in view of what would have been understood by one of ordinary skill at the time of filing, supports the broadest interpretation of the claimed methods with regard to the types of mutations and phenotypes that can be identified and analyzed. This includes generating both recessive and dominant mutations using an insertional mutagen, and encompasses mutations that give rise to either gain-of-function or loss-of-function phenotypes. At least four situations were contemplated by Applicants as capable of being identified and analyzed by the described (and claimed) methods:

recessive mutations (genotypes) leading to loss-of-function phenotypes;
recessive mutations leading to gain-of-function phenotypes;
dominant mutations leading to loss-of-function phenotypes; and
dominant mutations leading to gain-of-function phenotypes.

All four are disclosed in the application (and encompassed in the claims) originally filed.

As noted on page 3 of the subject Office action, “page 6 [of the specification] does disclose that insertional mutagens may cause both loss- and gain-of-function mutations.” Applicants further note that the specification indicates that “[t]he insertion of an insertional mutagen into a plant genome may produce a mutant trait . . . [that] may be dominant or negative” (page 6, lines 9-11). Later on that same page, in discussing preferred embodiments, Applicants

have expressly indicated that “insertional mutagens . . . can generate both loss-of-function and gain-of-function mutations” (page 6, lines 31-32).

While the specification recognizes that “Dominant mutant traits are generally gain-of-function” (page 6, line 13) and “Recessive mutant traits are generally loss-of-function” (page 6, lines 15-16), the use of “**generally**” in both of these sentences clearly illustrates that Applicants understood and appreciated that the reverse situations applied as well. One of ordinary skill, upon reading these passages alone, would recognize that Applicants contemplated that recessive mutant traits could be gain-of-function and dominant mutant traits, loss-of-function.

It is pointed out on page 3 of the Office action that Applicants’ specification (page 3, lines 26-29) “discloses that one aspect of the invention is methods for confirming association of dominant traits with an inheritance pattern or specific gene.” Applicants agree that this is but one aspect of the invention. The specification and original claims make it clear that the identification and tracking of recessive traits are also contemplated. For instance, examples of Applicants’ methods include “recording . . . mutant traits observed in the analyzed T2 plant **that were not present** in its parent T1 plant...” (step (f) of original claim 1; this text is maintained in the current claims). As explained at page 6 of the specification, recessive traits are only observed when both alleles are mutated; an associated phenotype would be observed in a selfed T2 generation, but not in the parental T1 generation. See also page 28, lines 18-20, which discusses this further. Thus, Applicants’ original (and current) claims have always been specifically drawn to identifying recessive mutations (as well as dominant mutations).

Additional support related to recessive mutations can be found at least at: page 21, lines 21-23, which describes analysis specifically beneficial for evaluating recessive mutants; pages 27, line 31, to page 28, line 1, which states that some loss-of-function mutations will be recessive, and provides guidance for analyzing plant tissue in such circumstances; and the section entitled “Analysis of Dominant or Recessive Inheritance Pattern” on page 28.

Further, the specification specifically describes detecting, selecting and characterizing mutant plants through the T1, T2, and subsequent generations. As discussed at page 4 of the

current Office action, rescuing DNA from the T1 generation is suitable for analysis of a dominant mutation, whereas rescuing DNA from the T2 (or a subsequent) generation is suitable for analysis of a recessive mutation (though it would also be useful for analysis of a dominant mutation). By way of example, the section entitled “Detecting, Selecting And Characterizing Transformants” at page 14 discusses “systematic evaluation of mutation traits, which generally takes place in the T1 or T2 generation but may also take place in subsequent generations.” Original claim 23 specified (and current claim 23 still specifies) “rescuing DNA flanking the insertional mutagen from a T1 or subsequent generation transformed plant.”

In view of the claim amendments made herein and the foregoing arguments, and particularly in view of the support for using insertional mutagens to cause recessive and dominant mutations, and loss-of-function and gain of function traits found throughout the specification and in the specification as a whole, Applicants request that the new matter rejection of claims 1-9, 11, 15-21, and 23-25 under 35 U.S.C §112 1st paragraph be withdrawn.

Rejection(s) under 35 U.S.C. §112, second paragraph

Claims 24 and 25 stand rejected under §112, 2nd paragraph, for allegedly being indefinite with regard to their use of the phrases “insertional recessive mutagen” and dominant mutant trait, as well as “dominant mutant phenotype”.

Applicants believe this rejection has been fully addressed by the claim amendments made herein, including particularly the change from “insertional recessive mutagen” to “insertional mutagen”. Applicants therefore request that this rejection be withdrawn.

Amended Claims are Free of the Art of Record

During the telephonic interview, distinctions between Applicants’ invention and the references of record were discussed. Though no prior art-based rejections are currently pending, Applicants take this opportunity to provide brief distinguishing comments on the record.

Applicants’ representative and the Examiner agreed, during the telephone conference, that none of the references currently of record teach the identification, tracking, or analysis of

recessive mutations caused by random mutagenesis using an insertional mutagen. As characterized by the Office, for instance in the Advisory Action, NEFF “teaches an insertional mutagen capable of both gain- and loss-of-function mutations, wherein **either mutation is dominant.**” Similarly, JOHNSON is characterized (also in the Advisory Action) as teaching “that his genetic marker is **inherited in a dominant manner...**” Neither reference has been relied upon for any teaching related to recessive mutations.

Applicants’ representative has not been able to locate any teaching in BRIGGS regarding recessive mutations, nor has this reference been relied upon for such teaching. Particularly BRIGGS does not teach anything related to systems for analysis or identification of recessive mutations caused by random mutagenesis using an insertional mutagen.

Applicants believe that none of the art of record, either alone or in any combination, fairly can be seen to teach the limitations of the currently pending claims.

CONCLUSION

It is respectfully submitted that the present claims are in a condition for allowance. If any issues remain, the Examiner is requested to contact the undersigned attorney prior to issuance of the next Office action in order to arrange a telephone interview. It is believed that a brief discussion of the merits of the present application, and the language of the current claims, may expedite allowance of the claims.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

By /Tanya M. Harding/
Tanya M. Harding, Ph.D.
Registration No. 42,630